Remarks

The Office Action mailed September 10, 2008 has been received and reviewed. Independent claims 1, 18, 32, and 50 have been amended. Reconsideration and withdrawal of the rejections are respectfully requested based on the submitted amendments and arguments.

Amendments to the Claims

Claims 1, 18, 32, and 50 have been amended to indicate that the claimed devices (shunts or cannulas) includes one or more occlusion-resistant materials distributed in one or more separate agent delivery device(s) that is not coated on, or impregnated in, the shunt wall and is contained within the lumen of said shunt, wherein said agent delivery device(s) is selected from the group consisting of spheres, inserts, eluting plugs, seeds, elongated members and combinations thereof; and releasing from said agent delivery devices one or more occlusion-resistant materials to inhibit the occlusion of the lumen of said shunt.."

The Examiner should note three changes present in the independent Claims: First, is the removal of the word "insertable. The Examiner previously took the position that an "insertable agent delivery device" would include coatings applied to the wall. Applicants invention teaches various methods for coating and impregnating the walls of the shunt or cannula[1] that can be used with the claimed invention; however, Applicants' invention was not claimed to be specifically directed to coatings or impregnated substance formed with or in the wall of the shunt or cannula. Applicants' claims are amended to proscribe a number of agent delivery devices that can be contained within the lumen of the shunt or cannula that is not a coating or impregnation of the shunt or cannula wall. The inserted agent delivery devices can

1 See Specification in the **Detailed Description, page 9, first sentence of the first full paragraph:** "The agent may be applied in a dip-coated manner, or as an impregnation into the shunt walls."

work with such coatings or impregnations of the wall of the shunt or cannula and therefore should not be construed as a limitation of the invention that these two different mechanisms of drug delivery can't work together. Not withstanding that Applicants agree with the Examiner's definition that an insertable agent delivery device should includes coatings of the shunt or cannula wall, Applicants have removed the earlier introduced limitation that the agent delivery device is "insertable". However, in order to indicate the agent delivery device is not part of the wall of the shunt or cannula, Applicants have added the limitation that the "agent delivery device is not a coating or impregnation of the shunt or cannula wall." This is the second change the Examiner will see in the four independent claims. Thirdly, independent Claims 1, 18, 32, and 50 were amended to make consistent that it is the agent delivery device(s) that are releasing one or more occlusion-resistant materials to inhibit the occlusion of the lumen of said shunt.."

The amendments are fully supported by Applicants' disclosure. Support for claiming the agent delivery devices that are not coatings or impregnations of the wall of the shunt (Claims 1, 32, or 50) or a cannula (Claim 18) is contained in the Specification. The agent delivery devices of the claimed invention can be found exemplified in Fig. 5, Fig. 6, and Fig. 7 and described on page 10, first paragraph, page 11, describing Figure 5, pages 11-12, describing Fig. 6, and page 12, second paragraph. Additionally, the specification makes a clear distinction between the claimed agent the delivery device(s) contained in the lumen, from coating or impregnation of the wall[2] of the device[3,4].

---

2 **See Brief Summary of the Invention, page 2, 2nd sentence and original claims 1, 30, and 50:** The shunt comprises an elongate wall structure configured as a tube having a lumen therethrough and a proximal end for receipt of bodily fluids and a distal end for discharge of said bodily fluids into another portion of the recipient's body.

3 **See Background of the Invention, page 1, 2rd Para. 2nd sentence.** The device and method utilizes, in one embodiment, dexamethasone sodium phosphate agent on a ventricular catheter tip to prevent encapsulation of the catheter. U.S. Patent No. 6,348,042 B1, issued to Warren, Jr., discloses a bio-active shunt device and method by

No new matter is introduced by the amendments.

The 35 U.S.C. § 103 Rejections

Burnett in view of Wu

The Examiner rejected claims 1, 2, 6, 11-12, 13, 16-19, 23, 28, 30-33, 37, 42-45, 48-51, 55, 60-63, 66, and 67 under 35 U.S.C. §103(a) as being unpatentable over Burnett (U.S. Patent No. in view of Wu (US6,656,506). Of the rejected claims, claims 1, 18, 32, and 50 are independent. Amendments introduced into the independent claims are the focus of the proceeding discussion of the art.

The Examiner has cited Burnett for disclosing the apparatus as claimed by the Applicant, with regard to claims 1, 18, 32, and 50 (the independent claims of Applicant). Burnett has been cited by the Examiner for disclosing an implantable fluid management system that may be implanted within a patient comprising an elongated conduit or cannula or tube 11 with a lumen

---

which the **interior lumen surface of a shunt is coated** with a matrix forming system having at least one enzyme configured for inciting activity to preclude the growth of obstructing cellular material. In one embodiment, the interior surface of the **catheter lumen is impregnated** with proteases or a matrix containing proteases that is **impregnated onto the wall** of the lumen to degrade cellular material including cells of the choroid plexus and peritoneum **(emphasis added)**.

4 Figures 8-13 are sectional views of CSF shunt tip portions having further embodiments of a drug or pharmaceutical agent 51 loaded onto or into the shunt. Figure 8 shows a portion of shunt 10 having a tip portion with wall material 68 defining fluid apertures 63 and closed tip 113. Within closed tip 113 there is positioned a plug 118 of material having occlusion preventing characteristics. In one embodiment, a dexamethasone plug is provided, as further described in examples below. Figure 9 shows a dip coating 121 of a drug eluting material to provide localized effect of the occlusion-preventing agent within coating 121. Figure 10 discloses another embodiment in which a seed 129 of a drug eluting material is placed within closed tip 113. Figure 11 also uses drug eluting seeds 134, but placing one or more in the wall material 68 rather than fully embedded within the closed tip 113.

therethrough, a proximal end with at least one opening or a plurality of perforations at the intake end (column 3, lines 10-20). The tube comprises an outflow end that discharges bodily fluids to another location within the body (generally, columns 1-2, Figure 16C). The conduit is cited for comprising one or more occlusion-resistant materials that may be integrated within or coated upon the surfaces of the system, which include the lumen of the tube (column 7, lines 38-65).

The Examiner points out that Burnett fails to disclose that the occlusion resistant materials are distributed in separate agent delivery devices selected from the group comprising spheres, plugs, seeds, rods, or combinations thereof. The Examiner uses Wu for teaching the agent delivery that incorporates polymer-based drug eluting microparticles of various shapes (including spheres).

The Examiner has stated clearly that the conduit is cited for comprising one or more occlusion-resistant materials that may be **integrated within or coated upon** the surfaces of the system, which include the lumen of the tube (column 7, lines 38-65).

Applicant's previous amendment included changes to clearly distinguish over Burnett. Independent Claims 1, 32, and 50 previously amended to indicate that the claimed devices "have materials distributed in one or more **separate** agent delivery devices **contained within the lumen of said shunt**." The Examiner disagrees that this distinction in the claims is enough, taking the position that a device coated with a layer of microparticles comprises a "separate" agent delivery device since it is applied separately after construction of the device and comprises a discrete, or "separate" microparticle delivery device. Further, the Examiner also construes that Applicants recitation of "insertable" agent delivery device can be construed to encompass Wu's coatings and impregnations of the shunt or cannula wall.

Applicants contend that the Examiner has taken a very different interpretation of the meaning of the word "agent delivery device", so that the term "microparticles" would serve as a prior art reference. Applicants contend it is not the ordinary and customary meaning of the term. It gives Applicants some pause to understand the Examiner argument that microparticles should be interpreted as devices, and that as such they are inserted into the lumen as a separate agent delivery device when actually they are coated on, or impregnated in, the wall of the device. However, in order to move forward prosecution from the difference in interpretation of the claims, Applicants have take the approach to present new language which makes clears that the separate agent delivery devices is not coated on, or impregnated in, the shunt or catheter wall.

As now amended, it does not seem possible that coatings to the wall of devices taught by Burnett or Wu singularly or in combination can also be read to include the agent delivery devices contained within the lumen. The materials of Burnett and Wu form part of the outer wall and hence can not be construed as being connect to the separate agent devices claimed by Applicants. Burnett and Wu treat the existing walls with agents which are then integrated within or coated on the surface. Applicants understand that through the teachings of Burnet and Wu a new device is formed, but respectively disagree that Burnet or Wu teaches one or more **separate** agent delivery devices contained within the lumen of the shunt or cannula as now claimed.

More specifically, in regard to the teachings of Wu, Wu's teaching is related to drug-loaded microparticles that can be incorporated onto the surface of a medical device. The drug coated microspheres are applied onto a medical device by dipping the device into a polymer matrix so that a coating of the polymer matrix has a relatively smooth surface texture over the entire surface. Alternatively, Wu teaches the medical device can be spray coated with a polymer

matrix. Coating a medical device by either method with a polymer matrix does not lead or render obvious Applicants' Invention of having one or more separate agent delivery devices contained within the lumen of the shunt or cannula that are not a coating or impregnation of the shunt or cannula wall. Applicants contend that Wu's reference to a microsphere or nanosphere is related to drug particles formed with the wall of the original device. Spheres of the present invention are agent delivery devices separately contained and insertable within the lumen of device that are not coated on, or impregnated in, the wall. Applicants contend their spheres cannot be equated with having microspheres or nanospheres coated onto the inner or outer surface of the device, which is now specifically excluded as part of the claim. Applicants draw the attention of the Examiner to Figures 2-13 of their specification where the separate insertable agent delivery devices contained within the lumen of the device can not be confused with being a coated microsphere or nanosphere on the wall of the shunt or cannula.

In view of the submitted amendments, and arguments presented above, Applicants respectively request the present rejection over Burnett in view of Wu be removed.

Claims 3-5, 20-22, 34-36, 52-54 Rejection over Burnett in view of Wu, further in View of Kraus

Claims 3-5, 20-22, 34-36, and 52-54 were rejected under 35 U.S.C. 103(a) as being unpatentable over US 7,195,608 to Burnett in view of US 6,656,506 to Wu et al, further in view of US 5,928,128 to Kraus.

The Examiner indicates that in the specification and figures, the prior art suggests the

apparatus substantially as claimed by Applicant with the exception of the composition of the implantable shunt. The Examiner has cited the Kraus reference for disclosing a shunt comprising a conduit with inflow and outflow ends (Fig. 6A) that comprises a valve to control fluid flow and that may be made of silicone or polyurethane in order to enhance biocompatibility (column 3, lines 15-30; column 6, lines 45-57).

Applicants acknowledge Kraus teaches a conduit with a valve to control fluid flow that may be made of silicone or polyurethane. However, the addition of Kraus does not cure the problem. Neither reference, alone nor in combination, teach devices having materials distributed in one or more separate insertable agent delivery devices contained within the lumen of said shunt (see arguments presented above to Burnett in view Wu) which now specifically excludes the possibility that the inserted device is not a coating or impregnation of the main device wall.

In view that Burnet in view of Wu in further view of Kraus do not teach one or more separate agent delivery devices contained within the lumen of a shunt or cannula, Applicants respectively request the present rejection removed.

Claims 7-10, 24-27, 38-41, and 56-59 under 35 U.S.C. 103(a) over Burnett inv view of Wu et al, further in view of Hunter

Claims 7-10, 24-27, 38-41, and 56-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 7,195,608 to Burnett in view of US 6,656,50 to Wu et al, further in view of US 2005/0208095 A1 to Hunter et al.

The Examiner has indicated that in the specification and figures, the prior art suggests the devices and methods substantially claimed by Applicant with the exception of incorporating myocphenolic acid as a therapeutic agent within the shunt. Specifically, with regard to claims 7, 8, 9, 24-26, 38-40, and 56-58, the Examiner contents that Hunter discloses a method of treating patients with various conditions by providing an implantable medical device comprising a therapeutic agent into a patient and allowing the therapeutic agent to elute into the patient (see para. 0014). In one embodiment, the therapeutic material may comprise mycophenolic acid in order to inhibit fibrosis (para. 0223). The Examiner has indicated that it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design (see MPEP 2144.07). The Examiner concludes that it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the shunt suggested by the prior art with the therapeutic agent disclosed by Hunter in order to provide the desired therapeutic result and inhibit fibrosis, as taught by Hunter.

With regard to Applicant's claims 10, 27, 41, and 59, drawn to a "combination" of mycophenolic acid and another agent, the Examiner indicates the claims fail to specify the amounts of the combination. As indicated the Examiner points out that a mixture of 100% mycophenolic acid and 0% other agents may comprise a combination, giving the term "combination" its broadest interpretation.

Applicants acknowledge Hunter teaches a method of treating patients with various conditions by providing an implantable medical device that allows the therapeutic agent to elute into the patient, wherein the therapeutic material may comprise mycophenolic acid to inhibit fibrosis. However, the addition of Hunter does not cure the problems of Burnett or Wu, or those

references in combination. Neither reference, nor in combination, teach devices having materials distributed in one or more separate insertable agent delivery devices contained within the lumen of said shunt that is not a coating or impregnation of the shunt or cannula wall (see arguments presented above to Burnett in view of Kraus).

In view that Burnet in view of Wu in further view of Kraus do not teach one or more separate agent delivery devices contained within the lumen of a shunt or cannula, Applicants respectively request the present rejection removed.

Summary

It is respectfully submitted that all the pending claims are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby. It is respectfully requested that should the Examiner still have questions about the allowability of the subject claims that Applicants representative meet with the Examiner to discuss any remaining issues.

Respectfully submitted for,
Edouard KOULLICK, et al.

March 6, 2009
Date

By: Kenneth J. Collier
Kenneth J. Collier
Registration No. 34,982
Telephone Number: (763) 505-2521
Facsimile Number: (763) 505-2530
CUSTOMER NUMBER: 27581